UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,
ex rel. Jonathan B. Fering,

Plaintiffs, Civil Action No. 17-cv-1796

v.

CENTER FOR PAIN MANAGEMENT, S.C.,
NOSHEEN HASAN, M.D.,
MIDWEST LABORATORY SALES & CONSULTING, LLC, and
MATTHEW SAMUELSON,

Defendants.

COMPLAINT-IN-INTERVENTION OF THE UNITED STATES OF AMERICA

Plaintiff, the United States of America, alleges for its complaint in intervention as follows:

Introduction

1. The United States brings this action against the defendants pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733 ("FCA"), the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) ("AKS"), and the common law for over two million dollars of false billings the defendants submitted to Medicare and Medicaid for urine drug tests.

2. Defendant Center for Pain Management, S.C. ("CPM") and its owner, Defendant Nosheen Hasan, M.D., provide pain management treatment in Milwaukee, Wisconsin. Dr. Hasan is CPM's only physician and oversees several nurse practitioners and physicians assistants at CPM. CPM has long been one of the largest prescribers of opioid medications in the State of Wisconsin. Indeed, the Wisconsin Medical Examining Board reprimanded Dr. Hasan in 2016 for improperly prescribing opioid medications to her pain patients.

3. As part of their pain management practices, CPM and Dr. Hasan use urine drug tests, ostensibly to assess patients' compliance with their opioid medications. Before the conduct at issue in this matter, CPM and Dr. Hasan used inexpensive, point-of-care urine drug testing. These point-of-care tests provided immediate results that CPM providers could use on the same day as the patient visit. Medicare, Medicaid, and other insurance, however, provided CPM with minimal reimbursement for the point-of-care tests.

4. In order to generate additional reimbursement for urine drug testing from insurers, including Medicare and Medicaid, CPM and Dr. Hasan entered into an agreement with Defendant Midwest Laboratory Sales & Consulting, LLC ("Midwest") and its owner, Defendant Matthew Samuelson, through which the defendants knowingly submitted over two million dollars' worth of false claims for urine drug tests from 2012 through 2017.

5. More specifically, and as explained in detail below, CPM and Dr. Hasan required every CPM patient at every visit to receive a urine drug test performed at Midwest's laboratory, without any individualized assessment of the patient's need for the test. Although Midwest performed the urine drug tests and bore full financial responsibility for the laboratory, the defendants agreed that CPM would bill Medicare and Medicaid for the laboratory tests. The defendants then split the reimbursement obtained from Medicare and Medicaid for the laboratory tests. CPM and Dr. Hasan thus received, and Midwest and Samuelson paid, illegal remuneration in exchange for the referral of patients from CPM to Midwest for urine drug testing in violation of the FCA and AKS.

6. The defendants knew that federal law prohibited the payment and receipt of remuneration in exchange for the referral of patients for services paid by federal healthcare programs, including Medicare and Medicaid. Nonetheless, Midwest and Samuelson paid CPM

and Dr. Hasan for referrals for urine drug testing. As Dr. Hasan explicitly stated in emails to Samuelson, CPM and Dr. Hasan "GENERATE THE BUSINESS" for Midwest's lab because "these are my patients" and "without them you will have no lab."

7. The defendants also submitted false claims to Medicare and Medicaid for urine drug testing that was not performed as well as false claims for testing that was not reasonable and necessary for treatment. Indeed, CPM billed for numerous urine drug tests that are not documented in its medical records. CPM also routinely billed for urine drug tests that were not used by CPM's providers in the treatment of their patients.

Jurisdiction and Venue

8. The United States brings this action under the FCA, 31 U.S.C. §§ 3729-33, and under the common law theory of unjust enrichment. This Court has jurisdiction over this action under 31 U.S.C. § 3730(a) and 28 U.S.C. § 1345.

9. This Court is the proper venue for this action pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a).

10. This Court may exercise personal jurisdiction over the defendants pursuant to 31 U.S.C. § 3732(a). This Court may also exercise personal jurisdiction over the defendants because they transact business in this District and because CPM and Dr. Hasan reside in this District.

The Parties

11. Plaintiff, the United States of America, brings this action on behalf of the Department of Health and Human Services ("HHS"), and, specifically, its operating division, the Centers for Medicare & Medicaid Services ("CMS").

12. Relator, Jonathan Fering, is an individual who resides in Chaska, Minnesota. Fering is a marketer of medical laboratory equipment and systems, including urine drug testing equipment.

13. Defendant Center for Pain Management, S.C., is a service corporation incorporated in the State of Wisconsin with its principal place of business in Milwaukee, Wisconsin. CPM currently operates clinics located at 6200 West Center Street, Milwaukee, Wisconsin and 4495 North Oakland Avenue, Shorewood, Wisconsin. CPM formerly operated clinics at 7235 West Appleton Avenue, Milwaukee, Wisconsin, and 910 Elm Grove Road, Elm Grove, Wisconsin.

14. Defendant Nosheen Hasan, M.D., is a Wisconsin resident. Dr. Hasan is board certified by the American Board of Anesthesiology. At all times relevant to this complaint, Dr. Hasan owned CPM and controlled its operations, including the establishment and oversight of CPM's policies and procedures for urine drug testing, CPM's billing of services to third party payers such as Medicare and Medicaid, and CPM's relationship with Midwest.

15. Defendants Midwest Laboratory Sales & Consulting, LLC, is a limited liability company incorporated in the State of Minnesota. Midwest operated a urine drug testing laboratory within CPM's facility located at 7235 West Appleton Avenue, Milwaukee, Wisconsin.

16. Defendant Matthew Samuelson is the owner of Midwest and is a Minnesota resident. At all times relevant to this complaint, Samuelson controlled the operations of Midwest, including Midwest's operation of the laboratory and Midwest's relationship with CPM.

Legal Background

The False Claims Act

17. The FCA provides, as relevant here, that any person that (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval, or (2) knowingly

makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim, is liable to the United States for damages and penalties. 31 U.S.C. §§ 3729(a)(1)(A)-(B).

18. The FCA defines the term "knowingly" to mean that a person, with respect to information, (1) has actual knowledge of the information, (2) acts in deliberate ignorance of the truth or falsity of the information, or (3) acts in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b)(1). No proof of specific intent to defraud is required to show that person acted knowingly under the FCA. *Id.*

19. The FCA subjects defendants who violate the Act to civil penalties plus three times the amount of the damages the government sustains because of the defendants' actions. 31 U.S.C. § 3729(a).

The Anti-Kickback Statute

20. Congress enacted the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), to address Congressional concern that payoffs to physicians and other healthcare providers result in the provision of services that are medically unnecessary, of poor quality, or potentially harmful to patients. To protect the integrity of federal health care programs from these difficult-to-detect harms, Congress enacted a *per se* prohibition against the payment of anything of value in exchange for the referral of patients for services paid for by the government, regardless of whether the particular payment gave rise to overutilization or poor quality of care. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

21. The Anti-Kickback Statute thus prohibits any person from making or accepting any payment, in cash or in kind, to induce or reward any person for referring, recommending, or

arranging for federally-funded medical services, including services provided under the Medicare and Medicaid programs. *See* 42 U.S.C. § 1320a-7b.

22. The Anti-Kickback Statute expressly provides that a "person need not have actual knowledge of this section or specific intent to commit a violation of this section." 42 U.S.C. § 1320a-7b(h).

23. The Anti-Kickback Statute also expressly provides that a "claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of" the False Claims Act. 42 U.S.C. § 1320a-7b(g).

The Medicare Program

24. In 1965, Congress enacted Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, known as the Medicare program. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426-1. CMS administers Medicare.

25. The Medicare program consists of four parts: A, B, C, and D. CPM billed Medicare under Part B, which covers certain medical services, such as clinical laboratory services, furnished by physicians and other suppliers and providers. 42 U.S.C. § 1395k(a)(2)(B). At all times relevant to this complaint, CMS contracted with private contractors, referred to as Medicare Administrative Contractors ("MACs"), to act as agents in reviewing and paying claims submitted by health care providers. 42 U.S.C. §§ 1395h, 1395u; 42 C.F.R. §§ 421.3, 421.200, 421.400.

26. To participate in the Medicare program as a new enrollee, clinics and laboratories must submit a Medicare Enrollment Application, CMS Form-855B, or its electronic equivalent. Such providers also complete Form CMS-855B to change information or to reactivate, revalidate, and/or terminate Medicare enrollment.

27. Medicare regulations require providers and suppliers to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R. § 424.516(a)(1).

28. A provider's authorized official must sign the "Certification Section" in Section 15 of Form CMS-855B, which "legally and financially binds [the] supplier to all of the laws, regulations, and program instructions of the Medicare program."

29. On behalf of CPM, Dr. Hasan signed the certification statement in Section 15 of Form CMS-855B, agreeing that she understood that "payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying" with Medicare laws, regulations, and program instructions, "including, but not limited to, the Federal anti-kickback statute."

The Wisconsin Medicaid Program

30. Medicaid is a program jointly funded by the federal government and participating states to provide health insurance to indigent families with dependent children and to aged, blind, and disabled individuals whose income and resources are insufficient to meet the cost of medical services. 42 U.S.C. §§ 1396, *et seq*. (the "Medicaid Act"). The Medicaid Act sets forth minimum requirements for state Medicaid programs to meet in order to qualify for federal funding, and each participating state adopts its own state plan and regulations governing the administration of the state's Medicaid program.

31. Wisconsin participates in the Medicaid program ("Wisconsin Medicaid"). In Wisconsin, the Medicaid program was established pursuant to Wisconsin Statutes Chapter 49 and its administrative regulations. The United States pays for approximately 60% of the program.

32. Wisconsin Medicaid provides reimbursement for health care services provided to eligible individuals who are enrolled in the program. To assist with the administration of the Medicaid Program, Wisconsin contracts with an independent contractor that processes and pays claims submitted on behalf of the Medicaid members.

33. In order to submit claims to Wisconsin Medicaid for health care services provided to Medicaid beneficiaries, a provider must enter into a written Medicaid Provider Agreement with the Wisconsin Department of Health Services.

34. Dr. Hasan, individually and on behalf of CPM, signed Medicaid provider agreements. Among other things, Dr. Hasan and CPM agreed to comply with all applicable federal and state laws, Wisconsin Medicaid regulations, and Wisconsin Medicaid provider publications.

35. One of the conditions of the Wisconsin Medicaid Program is that it only covers, and reimburses for, services that are "medically necessary" and "appropriate." Wis. Admin. Code DHS §§ 106.02(5) and 107.01.

36. Further, the Wisconsin Medicaid Program will not pay for services that "fail to comply with program policies or state and federal statutes, rules and regulations. . . ." Wis. Admin Code DHS § 107.02(2)(a).

Medicare and Medicaid Requirements for Coverage for Laboratory Tests

37. Laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), as set forth at 42 C.F.R. Part 493.

38. Medicare Part B and Wisconsin Medicaid pay for certain diagnostic laboratory tests performed in a laboratory or physician's office. 42 C.F.R. § 410.32(d); Wis. Admin. Code DHS § 107.25. "Clinical laboratory services involve the . . . examination of materials derived from the human body for the diagnosis, prevention, or treatment of a disease or assessment of a medical

condition." Medicare Benefit Policy Manual ("MBPM"), (Pub. 100-02), Ch. 15, § 80.1, available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

39. Medicare Part B and Wisconsin Medicaid only cover services, including diagnostic laboratory services, that are reasonable and necessary for the diagnosis or treatment of an illness. *See* 42 U.S.C. § 1395y(a)(1)(A); Wis. Admin. Code DHS §§ 106.02(5) & 107.01.

40. All diagnostic tests, including urine drug tests, "must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." 42 C.F.R. § 410.32(a); *see also* Wis. Admin. Code DHS § 107.25(2)(a). An "order" is "a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary . . . . [T]he physician must clearly document, in the medical record, his or her intent that the test be performed." MBPM, Ch. 15, Section 80.6.1.

41. Clinical laboratory services also must be used promptly by the physician who is treating the beneficiary. *See* MBPM, Ch. 15, § 80.1.

42. In order to assess whether services are reasonable and necessary such that reimbursement is appropriate, Medicare and Wisconsin Medicaid require complete documentation of services rendered to beneficiaries. *See* 42 U.S.C. § 1395l(e); 42 U.S.C. § 1395u(c)(2)(B)(i); Wis. Admin. Code DHS § 106.02(9)(f). A provider's claim for a diagnostic test, such as a urine drug test, is not medically reasonable and necessary if there is not sufficient documentation in the patient's medical record to establish that the service was reasonable and necessary. *See* 42 C.F.R. § 410.32(d)(3).

43. The Department of Health and Human Services, Office of Inspector General ("HHS-OIG") has published Compliance Program Guidance for Clinical Laboratories in the Federal Register. 63 Fed Reg. 45076 (Aug. 24, 1998). Among other things, the HHS-OIG guidance clarifies that "Medicare generally does not cover routine screening tests" and that "the use of standing orders is discouraged." *Id.* at 45079, 45081.

Submission of Claims to Medicare and Wisconsin Medicaid

44. To obtain Medicare and Medicaid reimbursement for certain outpatient items or services, including urine drug tests, providers submit a claim form known as the CMS 1500 form ("CMS 1500") or its electronic equivalent known as the 837P form. To submit electronic claims on the 837P form, a provider must complete and submit to CMS an Electronic Data Interchange Enrollment Form pursuant to which the provider, among other things, agrees that it will "submit claims that are accurate, complete, and truthful."

45. Among the information the provider includes on a CMS 1500 or 837P form are certain codes, including Current Procedural Terminology Codes ("CPT codes") and Healthcare Common Procedure Coding System ("HCPCS") Level II codes, that identify the services rendered and for which reimbursement is sought.

46. The provider must also include on the CMS 1500 or 837P form the unique billing identification number of the "rendering provider" and the "referring provider or other source." *See also* 42 U.S.C. § 1395l(q).

47. When they submit a claim to Medicare or Medicaid, providers represent that the claim is truthful, accurate, and complete. They also represent that the claim complies with the Anti-Kickback Statute and all other applicable Medicare and Medicaid laws, regulations, and program requirements.

The Defendants' Fraudulent Schemes

CPM's Pain Management Practice

48. CPM holds itself out as specializing in the treatment of acute and chronic pain.

49. At all times relevant to this complaint, Dr. Hasan directly treated pain management patients and oversaw nurse practitioners and physicians assistants in their treatment of pain management patients at CPM. The majority of CPM's patients were insured through Medicare or Wisconsin Medicaid.

50. Dr. Hasan and CPM's other providers typically saw 30 or more pain management patients per day. The providers typically spent 15 minutes or less with each patient.

51. CPM's practitioners, including Dr. Hasan, have been among the highest prescribers of opioid pain medications in the State of Wisconsin over the past several years. For example, in 2016, Dr. Hasan prescribed over 500,000 pills of oxycodone. Likewise, three CPM nurse practitioners practicing under Dr. Hasan's supervision prescribed over 1,500,000 pills of oxycodone in 2016 alone.

52. In 2016, the Wisconsin Medical Examining Board determined that Dr. Hasan engaged in unprofessional conduct by engaging in conduct that tends to constitute a danger to the health, welfare or safety of patients or the public. *See* In the Matter of Disciplinary Proceedings Against Nosheen Hasan, M.D., 13 MED 492, Final Decision and Order 4552 (February 17, 2016). Specifically, the Medical Examining Board found that Dr. Hasan prescribed "very high doses of opioid pain medications . . . without documenting her reasoning" for prescribing them. *Id.* The Medical Examining Board thus reprimanded Dr. Hasan and imposed limitations on her license. *Id.*

53. At all times relevant to this complaint, Dr. Hasan required patients to visit the clinic every month to receive their opioid prescriptions.

54. Although Dr. Hasan required patients to visit the clinic monthly, CPM received modest reimbursement from insurance, including Medicare and Medicaid, for patient visits. For example, Medicare typically paid CPM about $40 to $60 per visit for established patients from 2012 through 2017.

55. As part of their pain management practice, Dr. Hasan and CPM's other providers also periodically required their patients to undergo urine drug testing.

56. Prior to the opening of Midwest's laboratory, CPM used inexpensive, point-of-care cup tests. Cup tests have a number of built-in drug test strips, each of which tests a urine sample for a specific drug or drug class. Cup tests use immunoassay methodologies to assess the presence or absence of a drug or drug class above a pre-set "cut-off" or concentration level.

57. To perform urine drug testing with cup tests, CLIA and its implementing regulations required CPM to enroll in CLIA and obtain a "CLIA waiver." 42 C.F.R. § 493.35. As relevant here, CPM received CLIA waivers effective June 2, 2008 and June 2, 2010. The CLIA waivers identified Dr. Hasan as the "laboratory director" for CPM.

58. When they used cup tests, CPM's providers received near-immediate results indicating whether the patient's urine sample contained their prescribed medications or illicit drugs. The cup tests thus allowed CPM's providers to make assessments about a patient's compliance with their opioid therapy, including decisions about continuing to prescribe opioids, during the same visit that the patient provided the urine sample.

59. Since at least 2011, Medicare, Medicaid, and other insurers typically provide very modest reimbursement to providers using point-of-care cup tests. For example, in 2011, Medicare reimbursed CPM less than $12 per cup test on average.

60. At the same time, Medicare, Medicaid, and other insurers paid clinics and laboratories substantially more for urine drug tests performed with laboratory analyzer machinery. The amount of reimbursement varied based on the testing methodology used by the analyzer and the analyzer's ability to detect the concentration of the drug or drug class in the sample.

61. At times, CPM sent its patients' urine samples to third party laboratories (such as Millennium Laboratories, Inc.) for more sophisticated testing with laboratory analyzers. As Dr. Hasan knew, these third party laboratories received substantially more reimbursement for their testing than CPM received for its point-of-care cup tests.

The CPM-Midwest Arrangement

62. In the fall of 2011, Dr. Hasan met with Samuelson and Fering to discuss the establishment of a laboratory at CPM.

63. Dr. Hasan did not want to bear the expenses of establishing and operating a laboratory, such as purchasing the laboratory analyzer and equipment, hiring laboratory staff, purchasing laboratory supplies, and obtaining accreditation of the laboratory under CLIA.

64. Samuelson agreed to bear the expenses of establishing and operating the laboratory. To facilitate the agreement, Samuelson created Midwest, which ultimately purchased the laboratory analyzer and other equipment, hired and paid the laboratory director and technician who operated the laboratory, purchased all the supplies necessary to operate the laboratory, and handled the accreditation of the laboratory under CLIA.

65. In exchange for Samuelson and Midwest bearing all the expense of establishing and operating the laboratory, Dr. Hasan agreed to refer CPM's patients exclusively to Midwest for urine drug testing. Given the significant size of CPM's pain management practice, the exclusive referral of patients to Midwest ensured that Midwest would receive a large, steady stream of patients for urine drug testing.

66. Although Midwest operated the laboratory and paid all of its expenses, Dr. Hasan and Samuelson agreed that Samuelson would obtain accreditation for the laboratory under CPM's name.

67. Dr. Hasan and Samuelson also agreed that CPM, not Midwest, would bill Medicare, Medicaid, and other insurance for the urine drug tests.

68. Dr. Hasan and Samuelson further agreed that CPM and Midwest would share the reimbursement obtained from insurance for the urine drug tests, even though CPM did not perform any services related to the tests or bear any financial responsibility for the laboratory.

69. From the very outset of the relationship between CPM and Midwest, the defendants recognized that a purpose of the arrangement was to provide Dr. Hasan and CPM with additional revenue formerly earned by third party laboratories such as Millennium.

70. For example, in an email in November 2011 about the impact of opening Midwest's laboratory on Millennium, Samuelson stated that Millennium is "making millions of $$ off of your business. Money that you will enjoy yourself, when we get going."

71. Likewise, in another email dated October 7, 2011, Samuelson reported to Dr. Hasan that "you will enjoy over $40,000 in PROFIT each week! That's more than $160,000 per month in profit!"

CPM and Midwest Create a Management Services Agreement
to Provide Cover for Their Arrangement

72. CPM and Midwest memorialized their arrangement in a Management Services Agreement effective November 2, 2011 (the "First MSA").

73. In the First MSA, Midwest agreed to manage the day-to-day operations of the laboratory, provide the laboratory manager/director, provide all the technical personnel, provide all the equipment and supplies, and create the laboratory procedures.

74. In exchange, CPM provided Midwest with the exclusive right to perform urine drug testing on CPM's patients.

75. CPM also agreed to provide space within its clinic for the laboratory without charging rent to Midwest.

76. CPM and Midwest further agreed that Midwest was an independent contractor, not an employee, of CPM.

77. At the time that CPM and Midwest executed the First MSA, they anticipated that the analyzer Midwest planned to purchase (a Carolina Liquid Chemistries Biolis 24i) could perform "quantitative" testing, *i.e.*, more sophisticated testing that could assess the amount of a drug in the urine sample. Insurance, including Medicare and Medicaid, reimbursed laboratories for such tests by paying a fee (often about $20-$25) for each drug or drug class tested.

78. In light of this understanding, CPM and Midwest agreed in the First MSA that Midwest would receive $8.17 for each drug or drug class tested for each patient's urine sample. CPM would retain the remaining reimbursement.

79. For example, if Midwest analyzed a urine sample for 10 drugs, Midwest would receive $81.70 for analyzing that sample. If insurance paid $250 for the testing, CPM would retain the remaining $168.30.

80. The First MSA also explicitly recognized that the amount Midwest received "will vary with actual patient volume."

81. In other words, the defendants recognized that, the more tests CPM ordered from Midwest, the more money Midwest would receive. Likewise, because CPM simply retained the difference between the amount received from insurance and Midwest's share, the amount CPM earned from the arrangement also increased as CPM ordered more tests.

CPM and Midwest Execute a Second Management Services Agreement Because Midwest's Analyzer Did Not Support Quantitative Drug Testing

82. Following the execution of the First MSA, Samuelson and Midwest purchased the Biolis 24i analyzer and other equipment necessary to establish the laboratory. Samuelson installed the laboratory equipment in a former patient room at CPM's clinic at 7235 West Appleton Avenue, Milwaukee, Wisconsin.

83. Samuelson also hired a laboratory director and a laboratory technician for Midwest to operate the laboratory.

84. Samuelson obtained a CLIA certificate of registration effective December 23, 2011 in order to permit Midwest's laboratory to perform more complex urine drug testing with its Biolis 24i analyzer. The CLIA certificate of registration was issued in CPM's name. The certificate, however, identified Midwest's employee, Dr. Larry Brace, as the laboratory director. Indeed, the accreditation of Midwest's laboratory in the name of CPM was a sham because Midwest established, operated, and paid for the laboratory.

85. Prior to the opening of Midwest's laboratory in 2012, Samuelson determined that the Biolis 24i analyzer could not, in fact, perform quantitative urine drug testing.

86. Instead, the Biolis 24i could perform only "qualitative" urine drug testing. In other words, like the point-of-care cup tests previously used by CPM, the Biolis 24i could only detect

the presence or absence of a drug or drug class. It could not provide a valid quantitative assessment of the amount of a drug in a patient's urine sample.

87. In early 2012, most insurers reimbursed laboratories and other providers for qualitative urine drug tests performed with analyzers at a flat rate per test, regardless of the number of drugs or drug classes tested. Insurers thus provided less reimbursement for qualitative tests than quantitative tests.

88. In light of the inability of the Biolis 24i to perform quantitative tests, CPM and Midwest entered into a second Management Services Agreement effective March 9, 2012 (the "Second MSA").

89. The Second MSA was identical to the First MSA in all material respects except for its payment terms.

90. The Second MSA provided that Midwest would receive $50 per patient test.

91. At the time the defendants executed the Second MSA, Medicare and Medicaid typically paid about $100 to $200 for each qualitative drug test performed with analyzers like the Biolis 24i. CPM, accordingly, stood to retain a significant amount of reimbursement for each test.

92. Like the First MSA, the Second MSA also recognized that the amount Midwest received "will vary with actual patient volume."

93. The defendants thus again recognized that Midwest and CPM would each receive more money as CPM ordered more tests from Midwest's laboratory.

The Defendants Falsely Represent That They Intend to Comply with the AKS

94. Dr. Hasan and Samuelson knew that federal law prohibits an individual from paying remuneration to another individual in exchange for the referrals of Medicare and Medicaid patients.

95. Indeed, in the First and Second MSAs, CPM and Midwest represented that they intended to comply with all federal laws, including "the Medicare and Medicaid Anti-Fraud and Abuse Laws and the federal prohibition on physician self-referrals."

96. In fact, however, the defendants did not complete any efforts to ensure that their arrangement complied with the AKS or other federal law.

97. During the government's investigation of this matter, in a sworn response to an interrogatory signed by Dr. Hasan, CPM stated that it relied on Samuelson and its billing company, Fi-Med Management, Inc., ("Fi-Med") to ensure that the CPM-Midwest arrangement complied with the AKS.

98. Dr. Hasan and CPM, however, never provided a copy of the First or Second MSA to Fi-Med for its review.

99. Fi-Med, moreover, does not provide advice to its clients concerning compliance with the AKS. Contrary to CPM's interrogatory response, Fi-Med's chief operating officer testified during the government's investigation that Fi-Med did not provide CPM or Dr. Hasan with an opinion that the CPM-Midwest arrangement complied with the AKS. Had Dr. Hasan or CPM asked for such an opinion, Fi-Med would have advised them to obtain legal counsel to review the arrangement.

100. Likewise, Samuelson did not retain counsel or take any similar steps to determine whether the CPM-Midwest arrangement complied with the AKS. He consequently did not provide CPM or Dr. Hasan with any opinion that the CPM-Midwest arrangement complied with the AKS. To the contrary, Dr. Hasan told Samuelson that Dr. Hasan's lawyer reviewed the First MSA.

Dr. Hasan Requires Monthly Urine Drug Tests for All CPM Patients
Without Regard for Medical Necessity or Utilization

101. Midwest began operations at its laboratory in CPM's Appleton Avenue facility on or about March 12, 2012. CPM moved its clinical operations from the Appleton Avenue facility to its current Center Street facility in approximately July 2016. Midwest continued to operate the laboratory at the Appleton Avenue facility after CPM moved to the Center Street facility, with CPM sending urine samples to Midwest's laboratory at Appleton Avenue. The laboratory remained accredited in CPM's name. CPM terminated its relationship with Midwest on or about December 31, 2017.

102. CPM and Midwest followed the practices described in paragraphs 103 through 114, below, throughout their relationship.

103. Pursuant to Dr. Hasan's and Samuelson's agreement that CPM would send patient urine samples exclusively to Midwest for testing, Samuelson created a laboratory test requisition form for CPM's providers to use to order urine drug tests from Midwest's laboratory.

104. Among other information, the laboratory test requisition form contained blank spaces for the ordering provider to identify the diagnosis supporting the need for testing and the ordering provider's signature.

105. Dr. Hasan filled in the form with a diagnosis of "chronic pain" and signed the form with her name. Dr. Hasan then had copies of the pre-filled form made.

106. Dr. Hasan required all CPM patients to undergo urine drug testing performed by Midwest during each patient's monthly visit to CPM.

107. Dr. Hasan thus instructed CPM's medical assistants and other office staff to collect automatically a urine sample from each patient at their monthly visit.

108. CPM's medical assistants and other staff did not supervise the collection of urine samples from patients. As recognized by a CPM nurse practitioner and Midwest's laboratory technician, the lack of supervision undermined the reliability of the samples. For example, one former CPM nurse practitioner expressed concerns to Dr. Hasan that patients provided fake urine samples (e.g., "clean" urine from other people who, unlike the patient, were not using illicit drugs). Nonetheless, CPM continued to permit patients to provide urine samples without supervision.

109. After obtaining a urine sample, the medical assistants, again per directions from Dr. Hasan, then completed the remainder of the pre-filled laboratory test requisition form and sent the sample to Midwest for testing. Whichever CPM medical provider actually saw the patient on the day the sample was collected—whether it be Dr. Hasan or one of the nurse practitioners or physician assistants—neither determined the need for the urine drug test based on an individualized assessment of the patient nor actually ordered the test.

110. Midwest hired David Petsch to serve as a part-time laboratory technician to perform the urine drug testing.

111. Petsch primarily worked nights and weekends at Midwest's laboratory. Petsch, therefore, did not test a patient's urine sample at the same time as the patient visit during which the patient provided the sample. Instead, Petsch typically did not complete testing of a patient sample until 4 to 7 days after the patient provided the sample.

112. Petsch provided Midwest's urine drug testing results to CPM's administrative staff, which then filed the results in the patient files. CPM's staff often did not file the results in a timely manner. For example, in an email dated October 28, 2012, Petsch reported to Dr. Hasan and Samuelson that CPM's staff had failed to file over 300 lab reports dating back nearly four weeks.

Consequently, these laboratory results were not available for CPM's providers to review—suggesting that the results were not pertinent to CPM's providers.

113. Unlike the point-of-care cup tests previously used by CPM, Midwest thus did not provide urine drug testing results on the same day as the patient provided a urine sample. CPM's providers typically did not review Midwest's results until the next monthly visit with the patient at the earliest.

114. If the testing performed by Midwest revealed that a patient was not taking his or her prescribed medications or was taking illicit drugs, Petsch automatically sent the urine sample to an outside laboratory for expensive, quantitative testing. Petsch requested re-testing for all drugs, not just the drug for which the patient failed on Midwest's testing. Such wholesale re-testing further calls into question the clinical usefulness of Midwest's testing.

CPM and Midwest Split Reimbursement Obtained From Medicare and Medicaid

115. Throughout the defendants' relationship, and as the defendants had agreed, Midwest operated the laboratory, paid for all of the supplies and labor necessary to operate the laboratory, and maintained the laboratory's CLIA accreditation.

116. CPM merely collected the urine samples and, once it received the results of the testing from Midwest, filed those results in the patients' medical files. CPM, of course, would have performed these same activities—without reimbursement from insurance—had CPM sent the urine samples to any third party laboratory. Neither Dr. Hasan nor any CPM employee was involved in the day-to-day operation of Midwest's laboratory.

117. Nonetheless, and as the defendants had agreed, CPM billed Medicare and Medicaid (and other insurance) for the urine drug tests under CPM's name.

118. Medicare paid CPM an average of about $93 per test in 2013, with reimbursement gradually declining to an average of about $70 in 2017. Wisconsin Medicaid paid CPM an average of about $186 per test in 2013 and about $184 per test in 2014, with reimbursement declining to an average of about $63 per test in 2017. Medicaid and Wisconsin Medicaid thus paid, on average, more reimbursement for the urine drug tests than they did for CPM's office visits.

119. To obtain its share of the revenue generated by the arrangement, Midwest initially sent periodic invoices to CPM. In these invoices, Midwest identified the number of tests performed for the period covered by the invoice and sought payment of $50 per test performed (consistent with the terms of the Second MSA).

120. CPM never paid Midwest the amounts shown on Midwest's invoices. Indeed, Samuelson confirmed in an email dated October 1, 2014 to Dr. Hasan that "[n]ot once did you ever pay Midwest Laboratory Sales & Consulting as per the monthly invoice." Midwest, in fact, stopped sending invoices to CPM in September 2012, less than 6 months after Midwest began its laboratory operations.

121. Instead, CPM simply provided Midwest a portion of the reimbursement received from Medicare, Medicaid, and other insurers for the urine drug tests. As Dr. Hasan confirmed in an email to Samuelson dated October 3, 2014, "I pay you according to the number of labs that fimed [sic] [CPM's billing company] tells me that we get reimbursed for."

122. Dr. Hasan represented to Samuelson that CPM provided Midwest with approximately 50% of the insurance reimbursement received for urine drug tests. In other words, the defendants agreed to split the reimbursement received from insurance for the urine drug tests conducted by Midwest.

123. If Midwest performed a urine drug test, but for whatever reason the patient's insurance did not pay for the test, Midwest received nothing for the test. Midwest, in essence, provided free testing to CPM.

124. CPM, consequently, did not bear any financial risk for the operation of Midwest's laboratory. If insurance paid for a urine drug test, CPM retained 50% of the reimbursement. If insurance did not pay for a test, CPM did not pay anything to Midwest despite the costs incurred by Midwest for conducting the test.

125. Midwest and Samuelson knowingly and willfully agreed to split the Medicare and Medicaid reimbursement generated by the urine drug tests with CPM in order to induce CPM and Dr. Hasan to continue to refer Medicare and Medicaid patients for testing at Midwest and to reward them for prior referrals. Midwest and Samuelson also knowingly and willfully agreed not to seek payment from CPM for tests for which insurance provided no reimbursement in order to induce CPM and Dr. Hasan to continue to refer Medicare and Medicaid patients for testing at Midwest and to reward them for prior referrals.

126. Likewise, CPM and Dr. Hasan knowingly and willfully accepted its unearned share of the Medicare and Medicaid reimbursement generated by Midwest's urine drug testing in exchange for their referral of Medicare and Medicaid patients to Midwest for testing. CPM and Dr. Hasan also knowingly and willfully accepted free urine drug tests from Midwest in exchange for its referral of Medicare and Medicaid patients to Midwest for testing.

The Defendants Knew That Midwest and Samuelson Paid CPM and Dr. Hasan for Referrals

127. The defendants knew that Medicare and Wisconsin Medicaid conditioned payment of claims on compliance with the AKS.

128. Nevertheless, during their relationship, the defendants recognized that Midwest and Samuelson paid remuneration (*i.e.*, a share of reimbursement received for the drug tests and free drug testing) to CPM and Dr. Hasan in exchange for the referral of Medicare and Medicaid patients to Midwest for testing.

129. For example, in an email dated August 3, 2013, Samuelson complained to Dr. Hasan about a late payment from CPM to Midwest. Samuelson stated: "CPM is enjoying a huge windfall of free revenue" from the laboratory. Samuelson further stated that Midwest "has provided CPM with a very large, expense-free revenue stream and a very good service line. It makes no business sense what-so-ever to starve the cash cow!"

130. In an email response dated August 3, 2013, Dr. Hasan reminded Samuelson that "it's a mutually beneficial endeavor" and that Midwest "pays no rent" for its laboratory space.

131. In another email dated August 5, 2013, Dr. Hasan reminded Samuelson that "I GENERATE THE BUSINESS" for Midwest's laboratory.

132. The August 2013 email exchange thus confirms that Dr. Hasan and Samuelson understood that CPM received a share of the Medicare and Medicaid reimbursement for urine drug tests in exchange for CPM's referrals to Midwest.

133. Likewise, in an email dated April 16, 2014, Samuelson complained to Dr. Hasan that "our current arrangement" caused Midwest to assume "**ALL** the loss" when insurance did not provide reimbursement for urine drug tests. Samuelson continued: "We are in this together. We should be sharing in the profit, and equally in the assumed loss. . . . [Y]ou have enjoyed a very healthy, almost pure profit."

134. In an email response dated April 16, 2014, Dr. Hasan replied to Samuelson: "You make it sound like I am the only person benefitting[.] The MOST important fact that you are

missing is that these are my patients without them you will have no lab." Dr. Hasan again reminded Samuelson that Midwest paid no rent for its laboratory space.

135. In another email dated April 16, 2014, Samuelson replied to Dr. Hasan: "Yes, they are your patients, and I appreciate our business arrangement. We both need each other to make this work."

136. The April 2014 email exchange demonstrates that Dr. Hasan and Samuelson understood that CPM received a share of the Medicare and Medicaid reimbursement for urine drug tests as well as free urine drug tests from Midwest in exchange for CPM's referrals to Midwest.

137. In another example, Samuelson wrote Dr. Hasan a letter attached to a December 12, 2017 email. Regarding the absence of work by CPM in the laboratory operation, Samuelson wrote: "your staff was collecting [urine] specimens before I built the lab and you were getting paid NOTHING for this! For the last 7 years I've made sure you're getting paid VERY WELL for collecting the specimens."

138. In his December 2017 letter, Samuelson thus recognized that CPM retained a share of Medicare and Medicaid reimbursement for the drug tests simply because CPM collected urine samples and sent them to Midwest, *i.e.*, Midwest paid CPM a share of the reimbursement in exchange for referrals.

The Defendants' AKS Violations Were Material

139. The Department of Health and Human Services, Office of the Inspector General, has long warned healthcare providers that the AKS prohibits arrangements like one between CPM and Midwest. *See* Department of Health and Human Services, OIG Special Advisory Bulletin on Contractual Joint Ventures, 68 Fed. Reg. 23148 (April 30, 2003); Department of Health and Human Services, Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65372 (December 19,

1994). The Department of Health and Human Services, Office of the Inspector General, also warned healthcare providers that, although the AKS and its implementing regulations contain certain safe harbors to exclude business arrangements that may otherwise fall within the AKS's prohibitions, none of the safe harbors apply to arrangements like the one between CPM and Midwest. *See* 68 Fed. Reg. at 23149-23150.

140. Medicare and Wisconsin Medicaid were not aware at the time that CPM submitted the claims at issue in this matter that Midwest furnished urine drug tests in violation of the AKS.

141. Had Medicare and Wisconsin Medicaid been aware that CPM submitted claims for urine drug tests furnished by Midwest that were tainted by kickbacks in violation of the AKS, Medicare and Wisconsin Medicaid would not have paid for those tests.

142. Indeed, the government has repeatedly pursued criminal and civil remedies against providers who bill federal healthcare programs for services furnished in violation of the AKS. The government pursues such remedies because compliance with the AKS is necessary to ensure that a patient receives a service because he or she needs it, not because a provider benefits financially from providing it.

143. Congress likewise recognized that compliance with the AKS is material to Medicare's and Medicaid's decision to pay for a service when it amended the AKS to provide explicitly that a "claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of" the FCA. 42 U.S.C. § 1320a-7b(g).

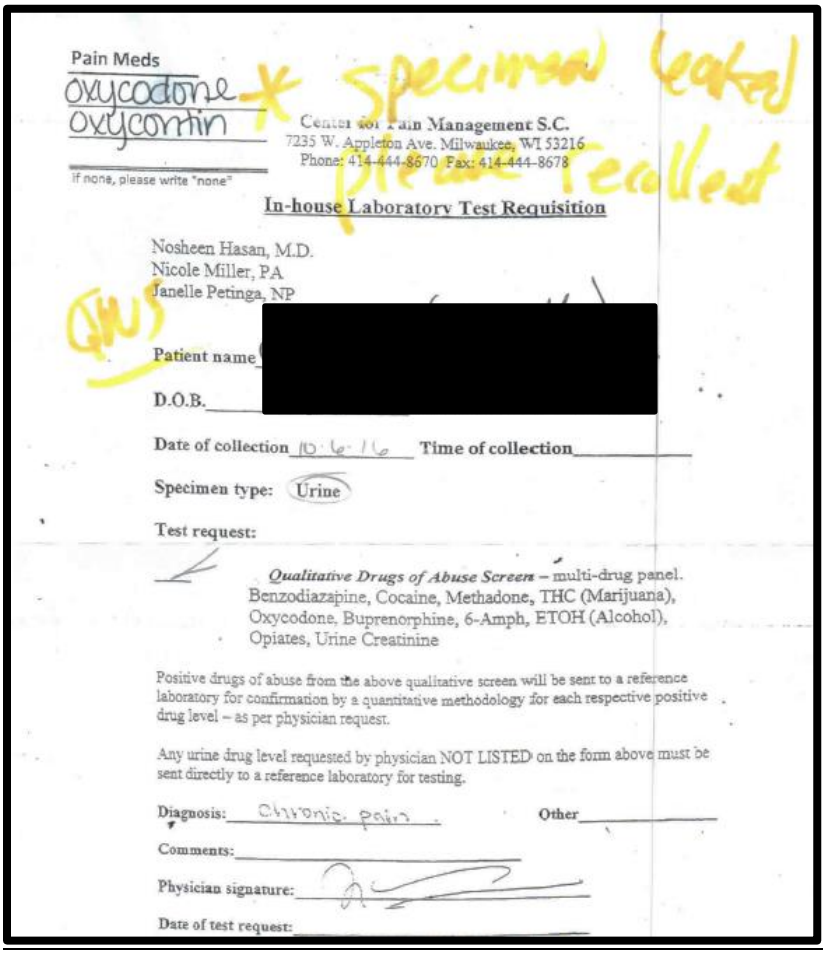
CPM Billed Medicare and Wisconsin Medicaid for Tests Not Rendered and for Medically Unnecessary Tests

144. As noted, Dr. Hasan instructed CPM's medical assistants and other office staff to collect urine samples from all patients at all visits and send them to Midwest for testing. As part

of this protocol, CPM's staff also included a charge for an office visit and a urine drug test on each claim to Medicare and Wisconsin Medicaid (and other insurers).

145. At times, however, Midwest could not perform urine drug testing on a patient's urine sample. Because CPM routinely included a charge for a urine drug test in each claim to Medicare and Wisconsin Medicaid, CPM submitted claims for tests never performed.

146. For example, on October 6, 2016, CPM collected a urine sample from patient S.A. By the time the sample arrived at Midwest's laboratory, however, the specimen container had leaked (as documented on the laboratory test requisition form below).



Pain Meds
oxycodone
oxycontin
If none, please write "none"

specimen leaked
please recollect

Center for Pain Management S.C.
7235 W. Appleton Ave. Milwaukee, WI 53216
Phone: 414-444-8670 Fax: 414-444-8678

In-house Laboratory Test Requisition

Nosheen Hasan, M.D.
Nicole Miller, PA
Janelle Petinga, NP

Patient name [redacted]

D.O.B.

Date of collection 10/6/16 **Time of collection**

Specimen type: Urine

Test request:

Qualitative Drugs of Abuse Screen – multi-drug panel.
Benzodiazapine, Cocaine, Methadone, THC (Marijuana), Oxycodone, Buprenorphine, 6-Amph, ETOH (Alcohol), Opiates, Urine Creatinine

Positive drugs of abuse from the above qualitative screen will be sent to a reference laboratory for confirmation by a quantitative methodology for each respective positive drug level – as per physician request.

Any urine drug level requested by physician NOT LISTED on the form above must be sent directly to a reference laboratory for testing.

Diagnosis: Chronic pain **Other**

Comments:

Physician signature:

Date of test request:

147. Midwest thus could not perform a urine drug test for S.A. with the sample collected on October 6, 2016. CPM nonetheless billed Medicare for a urine drug test (under HCPCS Code G0479) and received reimbursement of $77.66.

148. Patient S.A. is not an isolated incident. CPM and Dr. Hasan knowingly billed Medicare and Wisconsin Medicaid on multiple occasions for urine drug tests not documented in the patients' medical files. For some patients, nearly 50% of the urine drug tests for which CPM billed Medicare or Medicaid lack any supporting documentation to show that Midwest actually performed the tests.

149. In addition to billing Medicare and Wisconsin Medicaid for tests not rendered, CPM also billed them for medically unnecessary tests in violation of Medicare and Wisconsin Medicaid regulations. The defendants knew that CPM submitted claims for medically unnecessary tests in violation of Medicare and Wisconsin Medicaid regulations.

150. Contrary to Dr. Hasan's standing requirement that all CPM patients undergo urine drug testing at each monthly visit, a physician must make an individualized, patient-specific determination about the need for and frequency of urine drug testing. *See* 63 Fed. Reg. 45079, 45081; *see also* Local Coverage Determination: Urine Drug Testing (L36037) (effective November 1, 2015) (stating that urine drug testing for patients on chronic opioid therapy "must be based on patient-specific elements identified during the clinical assessment," must be "documented by the clinician in the patient's medical record," and should be performed randomly, with low risk patients needing testing only 1-2 times per year); American Pain Society and American Academy of Pain Medicine, Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain (2009) (stating that low risk patients require urine drug testing every 3 to 6 months and that random tests are more effective than scheduled or routine testing).

151. Because drug testing must be tailored to each patient's particular medical needs and history, routine tests at set intervals (such as tests at each monthly visit) for all patients are not medically necessary. *See* Local Coverage Determination: Urine Drug Testing (L36037) ("Routine standing orders for all patients in a physician's practice are not reasonable and necessary.").

152. Indeed, CPM's providers often made no use of the urine drug test results in their clinical decisions, including decisions about prescribing opioid pain medications.

153. For example, one of CPM's nurse practitioners saw patient P.D. on June 13, 2016. Although CPM billed Medicare for a urine drug test purportedly performed on May 16, 2016, the nurse practitioner reported in P.D.'s chart that the results were "not available" as of the June 13, 2016 visit. The nurse practitioner nonetheless prescribed P.D. 90 pills of OxyContin and 110 pills of morphine sulfate. Medicare paid CPM $77.66 for the test performed on May 16, 2016.

154. Similarly, another CPM nurse practitioner saw patient R.B. on July 19, 2017. During that visit, the nurse practitioner reviewed urine drug test results from a sample obtained at the patient's prior visit on June 21, 2017. Although the test showed that R.B. tested positive for benzodiazepine, which can cause complications when used with opioids, including respiratory depression and even death, and although R.B.'s chart did not show that he was prescribed any benzodiazepine, the nurse practitioner prescribed R.B. 300 pills of oxycodone. Medicare paid CPM $78.21 for the June 21, 2017 urine drug test.

The Defendants' False Claims to Medicare and Wisconsin Medicaid

155. Every claim submitted or caused to be submitted by the defendants to Medicare and Wisconsin Medicaid for urine drug testing furnished in violation of the AKS constitutes a false or fraudulent claim. *See* 42 U.S.C. § 1320a-7b(g); *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008).

156. Likewise, every claim submitted or caused to be submitted by the defendants to Medicare and Wisconsin Medicaid for urine drug testing that was (a) not actually furnished or (b) not medically necessary and reasonable constitutes a false or fraudulent claim. *See* 42 U.S.C. § 1395y(a)(1)(A); Wis. Admin. Code DHS §§ 106.02(5) and 107.01.

157. CPM's claims to Medicare and Medicaid for the urine drug tests performed by Midwest also falsely represented that CPM and/or its providers were the rendering provider of the tests, when, in fact, Midwest performed the tests. After CPM ceased its clinical operations at the Appleton Avenue facility in 2016, CPM's claims also falsely represented that the urine drug testing was performed at its Center Street location (when, in fact, Midwest continued to perform the tests at the Appleton Avenue location).

158. CPM, Dr. Hasan, Midwest, and Samuelson knew that the claims submitted to Medicare and Wisconsin Medicaid for urine drug tests were false or acted in deliberate ignorance or reckless disregard of the truth or falsity of the claims.

159. During the defendants' arrangement (*i.e.*, from March 12, 2012 through December 31, 2017), Medicare and Wisconsin Medicaid paid CPM the following reimbursement for claims for urine drug testing:

	Medicare		Medicaid	
Year	Number of UDT Claims	Amount Paid by Medicare	Number of UDT Claims	Amount Paid by Medicaid
2012	1,310	$ 102,274.05	795	$ 146,644.88
2013	1,457	$ 135,757.00	1,078	$ 200,511.84
2014	2,325	$ 206,030.78	1,992	$ 366,624.04
2015	2,534	$ 228,818.78	2,382	$ 166,540.29
2016	3,705	$ 278,184.61	3,110	$ 192,344.87
2017	3,218	$ 225,260.70	2,336	$ 146,418.00
Total	14,549	$ 1,176,325.92	11,693	$ 1,219,083.92

160. Based on the total reimbursement paid by Medicare and Wisconsin Medicaid for the urine drug tests and the 50/50 split of reimbursement between CPM and Midwest, Midwest and CPM likely each received approximately $1,197,704 for urine drug tests performed by Midwest and paid for by Medicare and Wisconsin Medicaid. In other words, CPM received $1,197,704 in return for its referrals of Medicare and Wisconsin Medicaid patients to Midwest for urine drug testing.

161. Consistent with those figures, CPM provided Midwest approximately $1,578,861 for Midwest's share of the reimbursement received from all insurers (not just Medicare and Wisconsin Medicaid) for the urine drug tests performed by Midwest.

False Claims for Patient C.L.

162. Patient C.L. was a Medicare beneficiary and received pain management treatment at CPM from May 2013 through April 2015.

163. During C.L.'s treatment, CPM referred C.L. to Midwest for urine drug testing on roughly a monthly basis. CPM submitted, and Medicare paid, claims for the following twenty urine drug tests performed by Midwest:

Date of UDT	Procedure Code Submitted	Rendering Provider Submitted on Claim	Amount Paid	Documentation of Lab Result In Patient File
5/21/2013	G0431	Hasan	$97.95	yes
6/18/2013	G0431	Hasan	$97.95	yes
7/16/2013	G0431	Hasan	$97.95	yes
8/14/2013	G0431	Hasan	$97.95	yes
10/10/2013	G0431	Petinga	$97.95	yes

11/13/2013	G0431	Hasan	$97.95	no
12/11/2013	G0431	Hasan	$97.95	yes
1/6/2014	G0431	Hasan	$97.22	no
3/7/2014	G0431	Hasan	$97.22	no
4/3/2014	G0431	Hasan	$97.22	yes
5/2/2014	G0431	Hasan	$97.22	yes
7/30/2014	G0431	Hasan	$97.22	no
8/26/2014	G0431	Petinga	$97.22	no
9/23/2014	G0431	Petinga	$97.22	no
10/20/2014	G0431	Hasan	$97.22	no
11/17/2014	G0431	Hasan	$97.22	yes
12/17/2014	G0431	Hasan	$97.22	no
2/11/2015	G0431	Hasan	$96.98	no
3/11/2015	G0431	Hasan	$96.98	yes
4/9/2015	G0431	Petinga	$96.98	yes

164. All of the claims identified in paragraph 163 were false because Midwest furnished the urine drug tests in violation of the AKS. Specifically, Midwest and Samuelson knowingly and willfully paid, and CPM and Dr. Hasan knowingly and willfully received, remuneration in the form of a share of the reimbursement paid by Medicare for these claims in exchange for CPM and Dr. Hasan's referral of C.L. to Midwest for testing.

165. The claims for the tests performed on the following dates were also false because the defendants did not perform these tests, yet knowingly billed Medicare for them:

November 11, 2013	September 23, 2014
January 6, 2014	October 20, 2014
March 7, 2014	December 17, 2014
July 30, 2014	February 11, 2015
August 26, 2014	

Indeed, C.L.'s medical records do not contain any urine drug testing results showing that these tests were actually performed by the defendants.

166. Finally, the claims for the tests identified in paragraph 163 were false because the defendants knowingly submitted these claims despite the facts that no CPM medical provider determined that C.L.'s medical needs supported the testing and/or no CPM medical provider reviewed and utilized the drug testing results in clinical decision-making.

False Claims for Patient T.L.

167. Patient T.L. was a Wisconsin Medicaid beneficiary and received pain management treatment at CPM from October 2014 through August 2017.

168. During T.L.'s treatment, CPM referred T.L. to Midwest for urine drug testing on roughly a monthly basis. CPM submitted, and Wisconsin Medicaid paid, claims for the following thirty-four urine drug tests performed by Midwest:

Date of UDT	Procedure Code Submitted	Rendering Provider Submitted on Claim	Amount Paid	Documentation of Lab Result In Patient File
10/20/2014	80101	Hasan	$192.20	yes
11/17/2014	80101	Hasan	$192.20	yes
12/17/2014	80101	Hasan	$192.20	yes
1/15/2015	G0431	Struve	$71.16	yes
2/12/2015	G0431	Struve	$71.16	yes

3/13/2015	G0431	Petinga	$71.16	yes
4/10/2015	G0431	Hasan	$71.16	no
5/8/2015	G0431	Hasan	$71.16	no
6/1/2015	G0431	Hasan	$71.16	yes
6/26/2015	G0431	Hasan	$71.16	no
7/24/2015	G0431	Struve	$71.16	no
11/6/2015	G0431	Petinga	$71.16	no
1/9/2016	G0479	Laabs	$63.40	no
1/29/2016	G0479	Petinga	$63.40	no
2/19/2016	G0479	Petinga	$63.40	no
4/6/2016	G0479	Petinga	$63.40	no
5/4/2016	G0479	Petinga	$63.40	yes
6/1/2016	G0479	Hasan	$63.40	no
6/29/2016	G0479	Petinga	$63.40	no
7/27/2016	G0479	Petinga	$63.40	no
8/18/2016	G0479	Hasan	$63.40	no
9/15/2016	G0479	Hasan	$63.40	yes
10/14/2016	G0479	Hasan	$63.40	yes
11/11/2016	G0479	Hasan	$63.40	yes
12/9/2016	G0479	Hasan	$63.40	yes
1/9/2017	80307	Hasan	$63.40	no

2/6/2017	80307	Hasan	$63.40	yes
3/3/2017	80307	Laabs	$63.40	yes
3/31/2017	80307	Hasan	$63.40	yes
4/27/2017	80307	Hasan	$63.40	yes
5/26/2017	80307	Petinga	$63.40	yes
6/22/2017	80307	Jones-Cooper	$63.40	no
7/21/2017	80307	Chris-Ukah	$63.40	yes
8/17/2017	80307	Hasah	$63.40	no

169. All of the claims identified in paragraph 168 were false because Midwest furnished the urine drug tests in violation of the AKS. Specifically, Midwest and Samuelson knowingly and willfully paid, and CPM and Dr. Hasan knowingly and willfully received, remuneration in the form of a share of the reimbursement paid by Wisconsin Medicaid for these claims in exchange for CPM and Dr. Hasan's referral of T.L. to Midwest for testing.

170. The claims for the tests performed on the following dates were also false because the defendants did not perform these tests, yet knowingly billed Medicare for them:

April 10, 2015	April 6, 2016
May 8, 2015	June 1, 2016
June 26, 2015	June 29, 2016
July 24, 2015	July 27, 2016
November 6, 2015	August 18, 2016
January 9, 2016	January 9, 2017
January 29, 2016	June 22, 2017
February 19, 2016	August 17, 2017

Indeed, T.L.'s medical records do not contain any urine drug testing results showing that these tests were actually performed the by defendants.

171. Finally, the claims for the tests identified in paragraph 168 were false because the defendants knowingly submitted these claims despite the facts that no CPM medical provider determined that T.L.'s medical needs supported the testing and/or no CPM medical provider reviewed and utilized the drug testing results in clinical decision-making.

Claims for Relief

Count One: False Claims Act: False or Fraudulent Claims (31 U.S.C. § 3729(a)(1)(A))

172. The United States incorporates and re-alleges all of the paragraphs of the complaint in intervention above as if fully set forth.

173. The defendants knowingly submitted, or caused to be submitted, false and fraudulent claims for payment to the United States and Wisconsin Medicaid, including claims for reimbursement for urine drug tests (a) furnished in violation of the Anti-Kickback Statute, (b) that were not actually performed, and/or (c) that were not reasonable and necessary for the diagnosis or treatment of individual patients. The defendants submitted or caused the submission of said claims with actual knowledge of their falsity or with reckless disregard or deliberate ignorance of whether they were false.

174. By virtue of the false or fraudulent claims that the defendants submitted or caused to be submitted to Medicare and Wisconsin Medicaid, the United States suffered damages and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

Count Two: False Statements Material to False Claims (31 U.S.C. § 3729(a)(1)(B))

175. The United States incorporates and re-alleges all of the paragraphs of the complaint in intervention above as if fully set forth.

176. The defendants knowingly made, used, or caused to be made or used false records or statements material to the false or fraudulent claims made to Medicare and Wisconsin Medicaid,

including: (1) false statements by CPM and Dr. Hasan on forms CMS-855B, CMS-1500, 837P, and the Wisconsin Medicaid provider enrollment form regarding their compliance with the AKS and other Medicare and Wisconsin Medicaid regulations; and (2) false billing records that misrepresented that urine drug tests were performed and/or were medically necessary and reasonable. Said false records or statements were made with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

177. By virtue of the defendants' false records and statements, the United States suffered damages and is entitled to recover treble damages plus a civil monetary penalty for each false record or statement.

Count Three: Unjust Enrichment

178. The United States incorporates and re-alleges all of the paragraphs of the complaint in intervention above as if fully set forth.

179. The United States claims the recovery of all monies by which the defendants have been unjustly enriched, including profits earned by the defendants because of the conduct described herein.

180. By retaining the monies received for the conduct described herein, the defendants were unjustly enriched at the expense of the United States in an amount to be determined and, which in equity and good conscience, should be returned to the United States.

Prayer for Relief

WHEREFORE, the United States demands and prays that judgment be entered in its favor against each of the defendants as follows:

I. On the First and Second Counts under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are authorized by law, together with all such further relief as may be just and proper.

II. On the Third Count for unjust enrichment, for the damages sustained, the amounts by which the defendants were unjustly enriched, and/or the amounts which the defendants retained illegally, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

The United States demands a jury trial on each of the issues so triable in this case.

Dated this 25th day of April, 2019.

MATTHEW D. KRUEGER
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